

## Complete Summary

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### GUIDELINE TITLE

Professionally applied topical fluoride. Evidence-based clinical recommendations.

### BIBLIOGRAPHIC SOURCE(S)

American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. J Am Dent Assoc 2006 Aug; 137(8):1151-9. [45 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Dental caries

### GUIDELINE CATEGORY

Prevention  
 Risk Assessment

### CLINICAL SPECIALTY

Dentistry

### INTENDED USERS

Dentists

#### GUIDELINE OBJECTIVE(S)

- To review the scientific evidence and to develop recommendations for the application of topical fluorides for the primary prevention of dental caries
- To serve as an adjunct to the dentist's professional judgment of how to best utilize professionally applied topical fluoride for each individual patient

#### TARGET POPULATION

U.S. population of all ages with natural teeth

#### INTERVENTIONS AND PRACTICES CONSIDERED

Professional application of topical fluoride (sodium fluoride or acidulated phosphate fluoride) as a gel, foam, or varnish

#### MAJOR OUTCOMES CONSIDERED

Incidence of dental caries

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases  
Searches of Unpublished Data

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and the Cochrane Database of Systematic Reviews were searched for systematic reviews published in English regarding professionally applied topical fluoride—including gel, foam and varnish forms—through October 2005. The "Find Systematic Reviews" tool of the PubMed Clinical Queries search engine ([www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml#reviews](http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml#reviews)) was used. Search terms were fluoride OR APF OR "acidulated phosphate fluoride" OR "sodium fluoride" OR "fluoride gel" OR "fluoride foam." Seventeen systematic reviews were identified. The Cochrane Oral Health Group list of systematic reviews ([www.update-software.com/abstracts/ORALAbstractIndex.htm](http://www.update-software.com/abstracts/ORALAbstractIndex.htm)) was searched manually for additional systematic reviews. Clinical studies published after January 2004 and, thus, not included in the systematic reviews also were identified through MEDLINE using the same search terms. The American Dental Association Council on Scientific Affairs formed a panel of experts to evaluate the identified systematic reviews and clinical trials. The expert panelists, listed in the section "Composition of Group that Authored the Guideline," were provided with the identified publications and asked to identify any additional systematic reviews or other relevant published trials. One publication had been accepted for

publication by the Journal of Dental Research and was included for consideration by the panelists.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence\*

I a Evidence from systematic reviews of randomized controlled trials

I b Evidence from at least one randomized controlled trial

II a Evidence from at least one controlled study without randomization

II b Evidence from at least one other type of quasi-experimental study

III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies

IV Evidence from expert committee reports or opinions or clinical experience of respected authorities

\* Amended with permission of the BMJ Publishing Group from Shekelle and colleagues. (Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. Brit Med J 1999;318(7183):593-6.

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The panel graded the evidence on the effectiveness of professionally applied topical fluoride for the prevention of caries on the basis of the system of Shekelle and colleagues. (see "Rating Scheme for the Strength of the Evidence").

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

#### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The expert panel assessed the data from the individual studies that were summarized in the systematic reviews and from the identified clinical studies and convened at a workshop held at the American Dental Association (ADA) Headquarters in Chicago Oct. 17-18, 2005, to evaluate the collective evidence and develop evidence-based clinical recommendations on professionally applied topical fluoride. The panel classified the strength of the recommendations on professionally applied topical fluoride on the basis of the system of Shekelle and colleagues (see "Rating Scheme for the Strength of the Recommendations").

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Grading of Recommendations\*

A Directly based on category I evidence

B Directly based on category II evidence or extrapolated recommendation from category I evidence

C Directly based on category III evidence or extrapolated recommendation from category I or II evidence

D Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

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## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

External Peer Review  
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The product of the workshop was the guideline document, which was submitted for review to scientists with expertise in fluoride and caries, relevant American Dental Association (ADA) agencies, and the external reviewers listed in the acknowledgments in the original guideline document. The comments received were considered by the expert panel. The clinical recommendations were approved by the ADA Council on Scientific Affairs.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Levels of evidence (Ia-IV) and grades of recommendation (A-D) are defined at the end of the "Major Recommendations" field.

The panel encourages dentists to employ caries risk assessment strategies in their practices. Appropriate preventive dental treatment (including topical fluoride therapy) can be planned after identification of caries risk status (see table below). It also is important to consider that risk of developing dental caries exists on a continuum and changes over time as risk factors change. Therefore, caries risk status should be re-evaluated periodically.

Table: Caries Risk Criteria
<p>Patients should be evaluated using caries risk criteria such as those below.</p> <p style="text-align: center;"><b>LOW CARIES RISK</b></p> <p>All age groups</p> <p>No incipient or cavitated primary or secondary carious lesions during the last three years and no factors that may increase caries risk*</p> <p style="text-align: center;"><b>MODERATE CARIES RISK</b></p> <p>Younger than 6 years</p> <p>No incipient or cavitated primary or secondary carious lesions during the last three years but presence of at least one factor that may increase caries risk*</p> <p>Older than 6 years (any of the following)</p> <ul style="list-style-type: none"> <li>• One or two incipient or cavitated primary or secondary carious lesions in the last three years</li> <li>• No incipient or cavitated primary or secondary carious lesions in the last three years but presence of at least one factor that may increase caries risk*</li> </ul> <p style="text-align: center;"><b>HIGH CARIES RISK</b></p> <p>Younger than 6 years (any of the following)</p> <ul style="list-style-type: none"> <li>• Any incipient or cavitated primary or secondary carious lesion during the last three years</li> <li>• Presence of multiple factors that may increase caries risk*</li> <li>• Low socioeconomic status**</li> <li>• Suboptimal fluoride exposure</li> <li>• Xerostomia***</li> </ul> <p>Older than 6 years (any of the following)</p> <ul style="list-style-type: none"> <li>• Three or more incipient or cavitated primary or secondary carious lesions in the last three years</li> <li>• Presence of multiple factors that may increase caries risk*</li> </ul>

Table: Caries Risk Criteria	
<ul style="list-style-type: none"> <li>• Suboptimal fluoride exposure</li> <li>• Xerostomia***</li> </ul>	
<p>* Factors increasing risk of developing caries also may include, but are not limited to, high titers of cariogenic bacteria, poor oral hygiene, prolonged nursing (bottle or breast), poor family dental health, developmental or acquired enamel defects, genetic abnormality of teeth, many multisurface restorations, chemotherapy or radiation therapy, eating disorders, drug or alcohol abuse, irregular dental care, cariogenic diet, active orthodontic treatment, presence of exposed root surfaces, restoration overhangs and open margins, and physical or mental disability with inability or unavailability of performing proper oral health care.</p> <p>** On the basis of findings from population studies, groups with low socioeconomic status have been found to have an increased risk of developing caries. In children too young for their risk to be based on caries history, low socioeconomic status should be considered as a caries risk factor.</p> <p>*** Medication-, radiation- or disease-induced xerostomia.</p>	

The table below summarizes the evidence-based clinical recommendations for the use of professionally applied topical fluoride. The clinical recommendations are a resource for dentists to use. These clinical recommendations must be balanced with the practitioner's professional judgment and the individual patient's preferences.

It is recommended that all age and risk groups use an appropriate amount of fluoride toothpaste when brushing twice a day, and that the amount of toothpaste used for children younger than 6 years not exceed the size of a pea. For patients at moderate and high risk of caries, additional preventive interventions should be considered, including use of additional fluoride products at home, pit-and-fissure sealants, and antibacterial therapy.

Table: Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride			
Risk Category	AGE CATEGORY FOR RECALL PATIENTS		
	< 6 Years		
	Recommendation	Grade of Evidence	Strength of Recommendation
Low	May not receive additional benefit from professional topical fluoride application*	Ia	B
Moderate	Varnish application at 6-month intervals	Ia	A
High	Varnish application at 6-month intervals	Ia	A
	OR		
	Varnish application at 3-month intervals	Ia	D**
	6 to 18 Years		
	Recommendation	Grade of Evidence	Strength of Recommendation
Low	May not receive additional benefit	Ia	B

Table: Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride			
Risk Category	AGE CATEGORY FOR RECALL PATIENTS		
	from professional topical fluoride application*		
Moderate	Varnish application at 6-month intervals	Ia	A
	OR		
	Fluoride gel application at 6-month intervals	Ia	A
High	Varnish application at 6-month intervals	Ia	A
	OR		
	Varnish application at 3-month intervals	Ia	A**
	OR		
	Fluoride gel application at 6-month intervals	Ia	A
	OR		
	Fluoride gel application at 3-month intervals	IV	D***
	18 + Years		
	Recommendation	Grade of Evidence	Strength of Recommendation
Low	May not receive additional benefit from professional topical fluoride application*	IV	D
Moderate	Varnish application at 6-month intervals	IV	D#
	OR		
	Fluoride gel application at 6-month intervals	IV	D***
High	Varnish application at 6-month intervals	IV	D#
	OR		
	Varnish application at 3-month intervals	IV	D#
	OR		
	Fluoride gel application at 6-month intervals	IV	D***
	OR		
	Fluoride gel application at 3-month intervals	IV	D***
<p>* Fluoridated water and fluoride toothpastes may provide adequate caries prevention in this risk category. Whether or not to apply topical fluoride in such cases is a decision that should balance this consideration with the practitioner's professional judgment and the individual patient's preferences.</p> <p>** Emerging evidence indicates that applications more frequent than twice per year may be more effective in preventing caries.</p>			

Table: Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride	
Risk Category	AGE CATEGORY FOR RECALL PATIENTS
<p>*** Although there are no clinical trials, there is reason to believe that fluoride gels would work similarly in this age group.</p> <p># Although there are no clinical trials, there is reason to believe that fluoride varnish would work similarly in this age group.</p> <p>Laboratory data demonstrate foam's equivalence to gels in terms of fluoride release; however, only two clinical trials have been published evaluating its effectiveness. Because of this, the recommendations for use of fluoride varnish and gel have not been extrapolated to foams.</p> <p>Because there is insufficient evidence to address whether or not there is a difference in the efficacy of sodium fluoride versus acidulated phosphate fluoride gels, the clinical recommendations do not specify between these two formulations of fluoride gels. Application time for fluoride gel and foam should be four minutes. A one-minute fluoride application is not endorsed.</p>	

### Definitions:

#### Levels of Evidence

I a Evidence from systematic reviews of randomized controlled trials

I b Evidence from at least one randomized controlled trial

II a Evidence from at least one controlled study without randomization

II b Evidence from at least one other type of quasi-experimental study

III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies

IV Evidence from expert committee reports or opinions or clinical experience of respected authorities

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#### Grading of Recommendations

A Directly based on category I evidence

B Directly based on category II evidence or extrapolated recommendation from category I evidence

C Directly based on category III evidence or extrapolated recommendation from category I or II evidence

D Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence



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## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate use of professionally-applied topical fluoride for prevention of dental caries

### POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These recommendations are offered with the understanding that the dentist, knowing the patient's health history and vulnerability to oral disease, is in the best position to make treatment recommendations in the interest of each patient. For this reason, evidence-based clinical recommendations are intended to provide guidance, and are not a standard of care, requirements or regulations. The clinical recommendations are a resource for dentists to use. These clinical recommendations must be balanced with the practitioner's professional judgment and the individual patient's preferences.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Patient Resources  
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. J Am Dent Assoc 2006 Aug; 137(8): 1151-9. [45 references] [PubMed](#)

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2006 Aug

### GUIDELINE DEVELOPER(S)

American Dental Association - Professional Association

### SOURCE(S) OF FUNDING

American Dental Association

### GUIDELINE COMMITTEE

Expert Panel on Professionally Applied Topical Fluoride

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Jeffrey W. Hutter, DMD, Med (Chairman) Goldman School of Dental Medicine, Boston University, Boston; Jarvis T. Chan, PhD, DDS, The University of Texas Health Science Center—Houston, Medical School; John D.B. Featherstone, MSc, PhD, University of California, San Francisco; Amid Ismail, BDS, MPH, MBA, DrPH, University of Michigan, School of Dentistry, Ann Arbor;

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panelists were selected on the basis of their expertise in the relevant subject matter. They were required to sign a disclosure stating that neither they nor their spouse or dependent children had a significant financial interest that would reasonably appear to affect the development of these recommendations.

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

Print copies: Available from the American Dental Association Council on Scientific Affairs, 211 E. Chicago Ave., Chicago, Ill. 60611.

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: executive summary of evidence-based clinical recommendations. Chicago (IL): American Dental Association; 2006. 4 p.

Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

## PATIENT RESOURCES

The following is available:

- Fluoride treatments in the dental office: extra protection for your teeth. J Am Dent Assoc. 2007 Mar;138(3):420.

Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

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## NGC STATUS

This NGC summary was completed by ECRI on February 9, 2007. The information was verified by the guideline developer on February 20, 2007.

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